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EXAMINER

COLLINS, C

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/477,730

Applicant(s)

SUGITA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Priority

1. A foreign priority is claimed.

Information Disclosure Statement

2. An initialed and dated copy of applicant's IDS form 1449, Paper No. 6, is attached to the instant Office action.

Drawings

3. The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a desired gene and the cytokinin signal transduction gene CKII as a selectable marker gene, does not reasonably provide enablement for a vector comprising a desired gene, and a plant hormone signal transduction gene as a selectable marker gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.
6. The claims are drawn to a vector comprising a desired gene, and a plant hormone signal transduction gene as a selectable marker gene.

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7. In the instant disclosure, applicants teach only how to make and use pIPTCKI-4, a vector comprising a desired gene and the cytokinin signal transduction gene CKI1 as a selectable marker gene (pages 27-33 *Example 1*, and *Figure 6*). Applicants do not teach any examples of how to make and use other vectors comprising other plant hormone signal transduction genes as selectable marker genes.

8. Claims 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a desired gene and a selectable marker gene that is the cytokinin signal transduction gene CKI1 located within a removable DNA element that is derived from the yeast site-specific recombination system pSR1, does not reasonably provide enablement for a vector comprising a desired gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

9. The claims are drawn to a vector comprising a desired gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element.

10. In the instant disclosure, applicants teach only how to make and use pMATCK-1, a vector comprising a desired gene and a selectable marker gene that is the cytokinin signal transduction gene CKI1 located within a removable DNA element that is derived from the yeast site-specific recombination system pSR1 (pages 37-42 *Example 3*, and *Figure 14*). Applicants do not teach any examples of how to make and use other vectors comprising other plant hormone

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signal transduction genes as selectable marker genes located within other types of removable DNA elements.

11. Claims 1, 4, and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector comprising a desired gene, and the plant hormone synthesis gene *ipt* together with the plant cytokinin signal transduction gene CKI1 as selectable marker genes, does not reasonably provide enablement for a vector comprising a desired gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

12. The claims are drawn to a vector comprising a desired gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene.

13. In the instant disclosure, applicants teach only how to make and use pIPCK-1, a vector comprising a desired gene, and the plant hormone synthesis gene *ipt* together with the plant cytokinin signal transduction gene CKI1 as selectable marker genes (pages 33-35 *Example 2*, and *Figure 8*). Applicants do not teach any examples of how to make and use other vectors comprising other plant hormone signal transduction genes as selectable marker genes and other plant hormone synthesis genes as selectable marker genes.

14. Guidance for making and using the claimed invention is necessary for enablement because the choice of an appropriate selectable marker gene for selecting transgenic plant cells can vary between plant species and plant cell types. Walden et al. teach that different plant

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species and plant cell types may require the use of different selectable markers and selection agents for the selection of transformed plant cells (1990, Eur. J. Biochem., Vol. 192, pages 563-576, see paragraph spanning pages 563-564).

15. Because the choice of an appropriate selectable marker gene for selecting transgenic plant cells can be unpredictable, the use of the claimed vectors may also be unpredictable. The claimed invention is not enabled by the specification in the absence of further guidance or example.

16. Given the unpredictability of using selectable marker genes to select transgenic plant cells, the absence of guidance in the specification for using the claimed vectors, the lack of working examples, and given the breadth of the claims which encompass plant transformation vectors comprising any plant hormone signal transduction gene as a selectable marker gene, any plant hormone synthesis gene as a selectable marker gene, and any removable DNA element, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claims 1-5, 7, and 9, and claims 6 and 8 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

19. Regarding claims 1, 4, and 5, the phrase "plant hormone signal transduction gene" renders the claims indefinite because it is unclear what constitutes a plant hormone signal transduction gene.

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20. Regarding claims 2, 3, and 9, the phrase "removable DNA element" renders the claims indefinite because it is unclear what constitutes a removable DNA element.
21. Regarding claims 4 and 7, the phrase "plant hormone synthesis gene" renders the claims indefinite because it is unclear what constitutes a plant hormone synthesis gene.
22. Regarding claim 5, the phrase "cytokinin signal transduction gene" renders the claim indefinite because it is unclear what constitutes a cytokinin signal transduction gene.
23. Regarding claim 7, the phrase "cytokinin synthesis gene" renders the claim indefinite because it is unclear what constitutes a cytokinin synthesis gene.
24. Regarding claim 9, the phrase "site-specific recombination system" renders the claim indefinite because it is unclear what constitutes a site-specific recombination system.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

26. Claims 1, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS).
27. The claims are drawn to a vector for introducing a gene into a plant, said vector comprising a desired gene and a plant hormone signal transduction gene as a selectable marker gene, wherein said plant hormone signal transduction gene is a cytokinin signal transduction gene that is the CK11 gene derived from *Arabidopsis thaliana*.

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28. Kakimoto et al. teach a vector for introducing a gene into a plant, said vector comprising a desired gene and a plant hormone signal transduction gene as a selectable marker gene, wherein said plant hormone signal transduction gene is a cytokinin signal transduction gene that is the CKII gene derived from *Arabidopsis thaliana* (page 983, column 1, second full paragraph).

29. Accordingly, claims 1, 5, and 6 are anticipated by Kakimoto et al.

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent No. 0 716 147 (12 June 1996, Applicant's IDS) in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS).

32. The claims are drawn to a vector comprising a desired gene, and a plant hormone signal transduction gene as a selectable marker gene. The claims are also drawn to a vector comprising a desired gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element. In addition, the claims are drawn to a vector comprising a desired gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene.

33. European Patent No. 0 716 147 teaches a vector comprising a desired gene, and a selectable marker gene that is the plant hormone synthesis gene *ipt* located within a removable

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DNA element that is derived from the yeast site-specific recombination system pSR1 (pages 14-16 *Example 5*, and page 42 *Figure 20*).

34. European Patent No. 0 716 147 does not teach a vector comprising a plant hormone signal transduction gene, alone or together with a plant hormone synthesis gene, as a selectable marker gene.

35. Kakimoto et al. teach a vector comprising a desired gene and a plant hormone signal transduction gene as a selectable marker gene, wherein said plant hormone signal transduction gene is a cytokinin signal transduction gene that is the CKII gene derived from *Arabidopsis thaliana* (page 983, column 1, second full paragraph).

36. Given the success of European Patent No. 0 716 147 in using a removable DNA element in a plant transformation vector to enable the removal of a cytokinin synthesis gene selectable marker from transgenic plants, and given the success of Kakimoto et al. in using a cytokinin signal transduction gene as a selectable marker gene in plants, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the cytokinin signal transduction gene selectable marker taught Kakimoto et al. in a vector such as that taught by European Patent No. 0 716 147, for the purpose of selecting transgenic plants and subsequently producing selectable marker-free transgenic plants, without any surprising or unexpected results. In addition, it would have been obvious to combine a plant hormone synthesis gene and a cognate plant hormone signal transduction gene as selectable markers because plant hormones and their cognate transducers are known work synergistically.

37. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been

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prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

38. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,791 (12 October 1999) in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS).

39. The claims are drawn to a vector comprising a desired gene, and a plant hormone signal transduction gene as a selectable marker gene. The claims are also drawn to a vector comprising a desired gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element. In addition, the claims are drawn to a vector comprising a desired gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene.

40. U.S. Patent No. 5,965,791 teaches a vector comprising a desired gene, and a selectable marker gene that is the plant hormone synthesis gene *ipt* located within a removable DNA element that is derived from the yeast site-specific recombination system pSR1 (column 19 line 66 through column 24 line 17, and *Figure 20*).

41. U.S. Patent No. 5,965,791 does not teach a vector comprising a plant hormone signal transduction gene, alone or together with a plant hormone synthesis gene, as a selectable marker gene.

42. Given the success of U.S. Patent No. 5,965,791 in using a removable DNA element in a plant transformation vector to enable the removal of a cytokinin synthesis gene selectable marker from transgenic plants, and given the success of Kakimoto et al. in using a cytokinin signal transduction gene as a selectable marker gene in plants, it would have been *prima facie* obvious

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to one skilled in the art at the time the invention was made to use the cytokinin signal transduction gene selectable marker taught Kakimoto et al. in a vector such as that taught by U.S. Patent No. 5,965,791, for the purpose of selecting transgenic plants and subsequently producing selectable marker-free transgenic plants, without any surprising or unexpected results. In addition, it would have been obvious to combine a plant hormone synthesis gene and a cognate plant hormone signal transduction gene as selectable markers because plant hormones and their cognate transducers are known work synergistically.

43. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

44. The applied reference U.S. Patent No. 5,965,791 has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after

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November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

45. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

46. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 6, and 7 of U.S. Patent No. 5,965,791 in view of Kakimoto et al. (8 November 1996, *Science*, Vol. 274, pages 982-985, Applicant's IDS).

47. The claims are drawn to a vector comprising a desired gene, and a plant hormone signal transduction gene as a selectable marker gene. The claims are also drawn to a vector comprising a desired gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element. In addition, the claims are drawn to a vector comprising a desired gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene.

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48. U.S. Patent No. 5,965,791 teaches a vector comprising a desired gene, and a selectable marker gene that is the plant hormone synthesis gene *ipt* located within a removable DNA element that is derived from the yeast site-specific recombination system pSR1 (column 19 line 66 through column 24 line 17, and *Figure 20*).

49. U.S. Patent No. 5,965,791 does not teach a vector comprising a plant hormone signal transduction gene, alone or together with a plant hormone synthesis gene, as a selectable marker gene.

50. Kakimoto et al. teach a vector comprising a desired gene and a plant hormone signal transduction gene as a selectable marker gene, wherein said plant hormone signal transduction gene is a cytokinin signal transduction gene that is the CKII gene derived from *Arabidopsis thaliana* (page 983, column 1, second full paragraph)

51. Given the success of U.S. Patent No. 5,965,791 in using a removable DNA element in a plant transformation vector to enable the removal of a cytokinin synthesis gene selectable marker from transgenic plants, and given the success of Kakimoto et al. in using a cytokinin signal transduction gene as a selectable marker gene in plants, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the cytokinin signal transduction gene selectable marker taught Kakimoto et al. in a vector such as that taught by U.S. Patent No. 5,965,791, for the purpose of selecting transgenic plants and subsequently producing selectable marker-free transgenic plants, without any surprising or unexpected results. In addition, it would have been obvious to combine a plant hormone synthesis gene and a cognate plant hormone signal transduction gene as selectable markers because plant hormones and their cognate transducers are known work synergistically.

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52. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 28, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

Elizabeth F. McElwain